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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,859	09/20/2000	Marek Z. Kubin	1010-US	1889

7590 12/07/2001

Immunex Corporation
Law Department
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Seattle, WA 98101

EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	4

DATE MAILED: 12/07/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/667,859	Kubin et al.
Examiner	**Art Unit**
G. R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 20, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *37-43 and 48-72* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *37-43 and 48-72* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 37-39 and 70, drawn to method of stimulating NK or T cells in a patient, classified in Class 424, subclass 278.1.

II. Claims 40-43, drawn to method of inhibiting the stimulation of NK, T, B, or dendritic cells in a patient, classified in Class 424, subclasses 278.1 and 184.1.

III. Claims 48-50, 54-57, and 59, drawn to a nucleic acid, a fragment, a vector, a host cell, and a method for producing a recombinant polypeptide, classified in Class 435, subclasses 69.1, 252.3, 320.1.

IV. Claims 51, 58, and 60-61, drawn to a polypeptide, a fragment, and an immunogenic composition, classified in Class 424, subclass 278.1 and Class 530, subclass 380.

V. Claims 52-53, drawn to an antibody, classified in Class 530, subclass 387.1.

VI. Claim 62, drawn to a fusion protein, classified in Class 530, subclass 387.3.

VII. Claims 63-64, drawn to method of detecting or chelating CD48, classified in Class 435, subclass 7.1.

VIII. Claim 65, drawn to method of inhibiting the binding of CD48 to NAIL, classified in Class 424, subclass 278.1 and Class 435, subclass 7.1.

IX. Claims 66-67, drawn to method of screening for inhibitors of the binding of CD48 to NAIL, classified in Class 435, subclass 7.1.

X. Claims 68-69 and 72, drawn to method of stimulating B cells, classified in Class 424, subclass 278.1 and Class 435, subclass 7.1.

XI. Claims 68-69 and 72, drawn to method of inhibiting the proliferation of cancer cells, classified in Class 424, subclass 278.1 and Class 435, subclass 7.1.

2. Inventions I-II and VII-XI are different methods. These inventions require different reagents, i.e., CD48 or NAIL, acting through different process steps, with different modes of operation, different endpoints, i.e., detecting or screening, and/or different outcomes, i.e., stimulation or inhibition. Therefore they are patentably distinct.

3. Invention III-VI are different products. They are distinct because their structures and/or modes of action are different. Therefore, the Invention are patentably distinct.

4. The polypeptide of Invention IV is related to the antibody of Invention V by virtue of being an antibody and the antigen to which it binds. Protein antigens and antibodies are physically and functionally distinct chemical entities. In addition to serving as antigens, polypeptides may also serve as receptor ligands, hormones, or in assays for the identification same, in addition to pharmaceutical compositions as claimed.

5. The nucleic acid of Invention III is related to the polypeptide of Invention IV by virtue of encoding same. However, nucleic acids and polypeptides are physically and functionally distinct chemical entities. Therefore, the Invention are patentably distinct.

6. Inventions VI and VII-XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in materially different processes, such as to produce antibodies.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
December 4, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600